K111421

# 510(k) Summary

FEB 1 7 2012

for

# Sirona Dental Systems

# Sirona Dental CAD/CAM System

# 1 Sponsor

Sirona Dental Systems GmbH

Fabrikstrasse 31

D-64625 Bensheim

Germany

Contact Person: Fritz Kolle

Telephone:

49 6251 16 32 94

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#### 2 Device Name

Proprietary Name:

Sirona Dental CAD/CAM-System

Common/Usual Name:

Abutment, implant, dental, endosseous

Classification Names:

Endosseous dental implant abutment

#### 3 Predicate Devices

Replace® NP, K091756, Brånemark®, K091756, Tissue level NN, K081005, OsseoSpeed™, K081666, Frialit® / Xive®, K032158, Osseotite K072642, Tapered Screw-Vent®, K060880, Nobel Active NP, K102436, Bone Level NC, K062129, Certain®, K073345.

Sirona Dental CAD/CAM System (K100152)

#### 4 Intended Use

The Sirona Dental CAD/CAM System is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multiple-unit cement retained restorations. For the titanium bases SSO 3.5 L and SBL 3.3 L, the indication is restricted for replacement of single lateral incisors in the maxilla and lateral and central incisors in the mandible. The system consists of three major parts: TiBase, inCoris mesostructure, and CAD/CAM software. Specifically, the inCoris mesostructure and TiBase components make up a two-piece abutment which is used in conjunction with endosseous dental implants to restore the function and aesthetics in the oral cavity. The inCoris mesostructure may also be used in conjunction with the Camlog Titanium base CAD/CAM (types K2244.xxxx) (K083496) in the Camlog Implant System. The CAD/CAM software is intended to design and fabricate the inCoris mesostructure. The inCoris mesostructure and TiBase two-piece abutment is compatible with the following implants systems:

- Nobel Biocare Replace (K020646)
- Nobel Biocare Branemark (K022562)
- Friadent Xive (K013867)
- Biomet 3i Osseotite (K980549)
- Astra Tech Osseospeed (K091239)
- Zimmer Tapered Screw-Vent (K061410)
- Straumann SynOcta (K061176)
- Straumann Bone Level (K053088, K062129, K060958)
- Biomet 3i Certain (K014235, K061629)
- Nobel Biocare Active (K071370)

#### 5 Device Description

The Sirona Dental CAD/CAM-System takes optical impressions and records the topographical characteristics of teeth, dental impressions, or stone models. Dental restorative prosthetic devices are manufactured using computer aided design and fabrication. The system also features the processing of mesostructures, a dental restorative prosthetic device used in conjunction with endosseous dental implant abutments.

The system that features the processing of mesostructures comprises

Titanium bases TiBase and Camlog

- inCoris ZI meso blocks
- Sirona Dental CAD/CAM Design and fabricating devices

Titanium bases are used as an implant prosthetic titanium base for adhesion to mesostructures to restore function and aesthetics in the oral cavity.

inCoris ZI meso blocks are used in manufacturing individually designed mesostructures, which are glued to a fitting titanium base after milling and sintering.

Sirona Dental CAD/CAM design and fabricating devices feature the processing of mesostructures, a dental restorative prosthetic device used in conjunction with endosseous dental implant abutments, i.e. it is an accessory to it. This component consists of the devices CEREC3, CEREC AC, inEos, inEos Blue, CEREC MCXL and inLab MCXL.

#### 5.1 TiBase

#### 5.1.1 Device Function

The Sirona TiBase is a premanufactured prosthetic component directly connected to dedicated endosseous dental implants and is intended for use as an aid in prosthetic rehabilitation.

The Sirona offering consists of the titanium base TiBase, the abutment screw and the scanbody. The parts are marketed non-sterile and for single use only.

The Sirona TiBase is bonded to an individually designed mesostructure, a ceramic prosthetic/restoration, that supports the final restoration. The mesostructure is milled from an inCoris ZI meso block with Sirona CAD/CAM milling machines CEREC or inLab, and sintered afterwards.

The two piece abutment is mounted onto the implant and fixed with a screw.

The scope of delivery contains a scanbody (ABS plastic) which is mounted on a TiBase in order to acquire the topographical surface of the area where the endosseous dental implant abutment is located with Sirona Dental CAD/CAM fabricating devices. From the acquired data the position of the implant can be calculated. After an optical impression has been taken the scanbody is removed.

Sirona TiBase devices are compatible with following systems (Table 1):

Table 1: Sirona TiBase Devices Compatibility

Sirona TiBase		Compatible System	.,
	Manufacturer	System	Diameter
NBRS 3.5		Replace® NP	3,5 mm
NBRS 4.3	Nobel Biocare	Replace® RP	4.3 mm
NBRS 5.0		Replace® WP	5.0 mm
NBRS 6.0		Replace® 6.0	6.0 mm
NBB 3.4	Nobel Biocare	Brånemark®	3.4 mm
NBB 4.1		Brånemark®	4.1 mm
SSO 3.5		Tissue level NN	3.5 mm
SSO 4.8	Straumann	Tissue level RN	4.8 mm
SSO 6.5		Tissue level WN	6.5 mm
ATOS 3.5/4.0	Astra Tech	OsseoSpeed™	3.5 S / 4.0 S mm
ATOS 4.5/5.0		OsseoSpeed™	4.5 / 5.0 mm
FX 3.4	Friadent	Frialit® / Xive®	3.4 mm
FX 3.8		Frialit® / Xive®	3.8 mm
FX 4.5		Frialit® / Xive®	4.5 mm
FX 5.5		Frialit® / Xive®	5.5 mm
DO 2.4	•	Osseotite	3.4 mm
BO 3.4	Biomet 3i	(Connec-tion type: Ex. Hex)	3. <del>4</del> IIIIII
	1	Osseotite	
BO 4.1		(Connec-tion type: Ex. Hex)	4.1 mm

Sirona TiBase		Compatible System	
<del></del>	Manufacturer	System	Diameter
		Osseotite	
BO 5.0		(Connec-tion type: Ex. Hex)	5.0 mm
ZTSV 3.5		Tapered Screw- Vent®	3.5 mm
ZTSV 4.5	Zimmer	Tapered Screw- Vent®	4.5 mm
ZTSV 5.7		Tapered Screw- Vent®	5.7 mm
NB A 4.5	Nobel Biocare	Nobel Active NP	3.5mm
NB A 5.0		Nobel Active NP	4.3 / 5.0mm
S BL 3.3	Straumann®	Bone Level NC	3.3mm
S BL 4.1		Bone Level NC	4.1 / 4.8mm
B C 3.4		Certain®	3.4mm
B C 4.1	Biomet 3i	Certain®	4.1mm
B C 5.0	1	Certain®	5.0mm

# 5.1.2 Scientific Concept

The underlying scientific concept is the use of an already introduced technology of a titanium base abutment combined with individually CAD/CAM fabricated ceramic prosthetics.

# 5.1.3 Physical and Performance Characteristics

#### 5.1.3.1 Design

The TiBase devices have various diameters, are compatible with dedicated implant systems, and fit to compatible implants as provided in Table 2.

**Table 2: Implant Compatibility** 

TiBase	Implant- Manufacturer	Implant-System	510(k) Implant
NBRS	Nobel Biocare	Replace	K020646
NBB	Nobel Biocare	Branemark	K022562
FX	Friadent	Xive	K013867
ВО	Biomet 3i	Osseotite	K980549
ATOS	Astra Tech	OsseoSpeed	K091239
ZTSV	Zimmer	Tapered Screw-Vent	K061410
SSO	Straumann	SynOcta	K061176
NB A	Nobel Biocare	Nobel Active	K071370
S BL	Straumann®	Bone Level	K053088
ВС	Biomet 3i	Certain®	K014235

#### 5.1.3.2 Material Used

TiBase and abutment screw are made of Ti6Al4V.

# 5.1.3.3 Physical Properties

TiBase material composition and mechanical properties comply with ISO 5832-3:1996, Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy

Sirona TiBase devices are compatible with systems listed in Table 1.

### 5.2 inCoris ZI meso

### 5.2.1 Device Description

The inCoris ZI meso offerings are blocks of various sizes from which individual dental mesostructures are grinded by milling machines (inLab MCXL, CEREC MCXL). The mesostructure is a part of a 2 part endosseous dental implant

abutment which comprises a titanium base and a zirconium oxide mesostructure. The connection geometries are prefabricated.

## 5.2.2 Scientific Concept

The underlying scientific concept is the use of an already introduced technology of a titanium base abutment combined with individually CAD/CAM fabricated ceramic prosthetics.

## 5.2.3 Physical and Performance Characteristics

#### 5.2.3.1 Design

The inCoris ZI meso are blocks of various sizes. The marketed ceramic is presintered. One side of a block is mounted to a mandrel that will be inserted in the spindle's clamping chuck of the grinding machine. The connection geometry to titanium bases is prefabricated, i.e. already included in the shipped block. Connection geometries fit on Camlog (type K2244.xxxx) and Sirona (Tibase) titanium bases (Table 3 and Table 4).

Table 3: Sirona inCoris ZI meso - TiBase Devices Compatibility

	Titanium Ba	se		Ceramic Bloc	k
TiBase (Sirona)	REF	Diameter	inCoris ZI meso (Sirona)	REF	Color inCoris ZI meso (Sirona)
NBRS 3.5	6282474	3,5 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
NBRS 4.3	6282482	4.3 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5
NBRS 5.0	6282490	5.0 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
NBRS 6.0	6282508	6.0 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
NBB 3.4	6282516	3.4 mm	inCoris ZI	62 31 810	F0.5

	Titanium Bas	se		Ceramic Bloc	k
TiBase (Sirona)	REF	Diameter	inCoris ZI meso (Sirona)	REF	Color inCoris Z1 meso (Sirona)
. <u></u>			meso L	62 31 836	F2
NBB 4.1	6282524	4.1 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
SSO 3.5	6284231	3.5 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
SSO 4.8	6284249	4.8 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
SSO 6.5	6284256	6.5 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
ATOS 3.5/4.0	6282532	3.5 S / 4.0 S mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
ATOS 4.5/5.0	6282540	4.5 / 5.0 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
FX 3.4	6282433	3.4 mm	inCoris ZI meso S	62 31 802 62 31 828	F0.5 F2
FX 3.8	6282441	3.8 mm	inCoris ZI meso S	62 31 802 62 31 828	F0.5 F2
FX 4.5	6282458	4.5 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
FX 5.5	6282466	5.5 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
BO 3.4	6282557	3.4 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2

	Titanium Bas	se		Ceramic Block	k
TiBase (Sirona)	REF	Diameter	inCoris Z1 meso (Sirona)	REF	Color inCoris ZI meso (Sirona)
BO 4.1	6282565	4.1 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5
BO 5.0	6282573	5.0 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
ZTSV 3.5	6282581	3.5 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
ZTSV 4.5	6282599	4.5 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
ZTSV 5.7	6282607	5.7 mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
NB A 4.5	6308188	3.5mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
NB A 5.0	6308253	4.3 / 5.0mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
S BL 3.3	6308154	3.3mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
S BL 4.1	6308337	4.1 / 4.8mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
B C 3.4	6308048	3.4mm	inCoris ZI meso S	62 31 802 62 31 828	F0.5 F2
B C 4.1	6308097	4.1mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2

	Titanium Ba	se		Ceramic Bloc	k
TiBase (Sirona)	REF	Diameter	inCoris ZI meso (Sirona)	REF	Color inCoris ZI meso (Sirona)
B C 5.0	6308121	5.0mm	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2

Table 4: Sirona inCoris ZI meso - Camlog Devices Compatibility

Т	itanium Base			Ceramic Bloc	k
Camlog	REF	Dia- meter	inCoris ZI meso (Sirona)	REF	Color inCoris ZI meso (Sirona)
K2244.3348	K2244.3348	3.3	inCoris ZI meso S	62 31 802 62 31 828	F0.5 F2
K2244.3848	K2244.3848	3.8	inCoris ZI meso S	62 31 802 62 31 828	F0.5 F2
K2244.4348	K2244.4348	4.3	inCoris ZI meso S	62 31 802 62 31 828	F0.5 F2
K2244.5048	K2244.5048	5.0	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2
K2244.6048	K2244.6048	6.0	inCoris ZI meso L	62 31 810 62 31 836	F0.5 F2

## 5.2.3.2 Material Used

The inCoris ZI meso are pre-sintered zirconium oxide ceramic blocks. The metal block holder is made of aluminum. The material is composed of:

 $ZrO_2+HfO_2+Y_2O_3 > 99.0\%$ 

 $Al_2O_3$  < 0.5%

Other oxides < 0.5%

## 5.2.3.3 Physical Properties

The final technical data of inCoris ZI meso are (after final sintering):

Density: 6.06 g/cm<sup>3</sup>

Coefficient of thermal expansion (CTE): 11.0\*10-6 K<sup>-1</sup>

Flexural strength: > 900 MPa

Fracture toughness (KIC): 5.9 MPa·m<sup>1/2</sup>

# 5.3 Sirona Dental CAD/CAM Design and fabrication Devices

## **5.3.1** Device Description

The Sirona Dental CAD/CAM Design and fabricating devices for processing mesostructures includes

- Optical acquisition or recording of the topographical characteristics of dental impressions, or stone models using the devices Acquisition unit CEREC 3, CEREC AC, and stationary scanning system in Eos Blue
- Design of mesostructures and processing the acquired or recorded data for these purposes using Sirona Dental CAD/CAM Software which runs on a CEREC 3, CEREC AC or PC. Design is performed by a dentist or dental technician
- Milling of the mesostructure using CEREC MCXL or inLab MCXL milling machines from ceramic blocks intended for dental restorations and mesostructures

The Sirona Dental CAD/CAM Design and fabricating devices also processes other dental restorations like crowns, bridge-frameworks, inlays, onlays all regulated under 21 CFR 872.3661, Optical Impression Systems for CAD/CAM, for such intended use.

#### 5.3.2 Scientific Concept

The underlying scientific concept is the use of CAD/CAM technology for the optical acquisition of the topographical characteristics of dental impressions, and models, the design of individual mesostructures using recorded data (CAD), and eventually fabricating (milling) these designed mesostructures (CAM).

## 5.3.3 Physical and Performance Characteristics

### 5.3.3.1 Design

Acquisition unit: the device consists of a camera for acquiring optical topographical characteristics of dental impressions. The recorded data are used for the design of individual mesostructures using CAD techniques specific to the dental field.

Fabricating devices: the devices mill the individual designed mesostructures from incoris ZI meso blocks. For this purpose the chucked block and the milling tools move according to prescribed trajectories to generate the shape which is intended to be milled.

#### 5.3.3.2 Materials Used

Not applicable.

## 5.3.3.3 Physical Properties

Not applicable.

## 6 Summary of the technological characteristics

#### 6.1 TiBase

All proposed and predicate titanium bases and screws are made of Ti6Al4V, medical grade 5. Connection interfaces to the implants are identical for each defined diameter and connection type. Connection interfaces to dental restorations differ in that proposed devices have an additional notch.

An extensive list is provided in Table 5.

#### 6.2 inCoris ZI meso

Proposed and predicate (K100152) device are inCoris ZI meso.

There has been no modification to inCoris ZI meso from Premarket Notification K100152. Specifically, the following aspects remain identical:

- Composition
- Material properties
- Thickness / design restrictions
- Shape and bonding surface of connection interfaces to Camlog and Sirona Tibase for Sirona inCoris ZI meso blocks
- Bonding material

InCoris ZI meso is bonded to titanium bases for supporting further dental restorations.

InCoris ZI meso material is made of zirconium oxide. The composition of inCoris complies with ISO standard 13356:1997, "Implants for surgery, Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)". Such compositions are classified as biocompatible by this standard.

An extensive list is provided in Table 6.

# 6.3 Sirona Dental CAD/CAM Design and fabrication Devices

There has been no modification to the Sirona Dental CAD/CAM Design and fabricating devices from Premarket Notification K100152. Specifically, the following aspects remain identical:

- optical impressions record topographical characteristics of teeth, dental impressions, or stone models for use in the computer aided design and fabrication of dental restorative prosthetic devices in conjunction with endosseous dental implant abutments, i.e. it is an accessory
- features the transfer of data of the optical impression to a remote milling machine via internet or exportation/importation of milling data

The software database of titanium bases has been extended to cover new additional titanium bases.

An extensive list is provided in Table 7.

Table 5: Comparison of Sirona TiBase to Predicate Devices

	•			·	and Screw made of Ti6Al4 V	tion geo- metry to abut- ments	geo- metry Type	geo- metry Anti- rota- tional fea-	netra
Manu- facturer	System	Diameter	Titanium Base	Predicate Devices			-		
				K-Number					
Nobel Biocare	Replace® NP	3,5 mm	Nobel Biocare product catalog page 14. Product-No. 32376	K091756	yes	yes	Inter- nal 3 te- nons	yes	same
Nobel Biocare	Replace® RP	4.3 mm	Product-No. 32377	K091756	yes	yes	Inter- nal 3 te-	yes	same

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Proposed		ď	Predicate Device	ə		Abut-	Iden-	Con-	Con-	Screw
Device						ment	tical	-59U	-590	98
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TiBase				•		Screw	nec-	8	98	
						made	tion	metry	metry	
						٥	-028			
						Ti6A14	metry			
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									rota-	
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	Manu-	System	Diameter	Titanium Base	Predicate					
	facturer				Devices					
					K-Number				•	
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NRRS 5.0	Nobel Biocare	Replace® WP	5.0 mm	Product-No. 32378	K091756	ves	, se		yes	same
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NBKS 6.0	Nobel Biocare	Keplace® 6.0	0.0 mm 0.0	Froduct-196, 52575	NO21130	ß	S S	3 te-	Š.	201110
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Proposed			Predicate Device	ice .		Abut-	Iden-	Con-	Con-	Screw
Device					-	ment	tical	nec-	nec	-09B
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TiBase						Screw	nec-	-098	036	
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-						Ti6Al4	metry			
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							ments	-	rota-	
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	, Manu- facturer	System	Diameter	Titanium Base	Predicate Devices					
					K-Number					
				Nobel Biocare product catalog page				Exter- nal		
NBB 3.4	Nobel Biocare	Brånemark®	3.4 mm	14. p J 4 M 22206	K091756	yes	yes	Hexa-	yes	same
				F10duct-N0, 32,390			· · · · ·	Bollal		
								Exter- nal		
NBB 4.1	Nobel Biocare	Brånemark®	4.1 mm	Product-No. 32397	K091756	yes	yes	Hexa- gonal	yes	same

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Screw geo-		same	same	same
Con- nec- tion geo- metry Anti- rota- tional fea- tures		yes	yes	yes
Con- nec- tion geo- metry Type		exter- nal octa- gonal	Inter- nal Octa- gonal	Inter-
Identical connection geo-		sek	yes	yes
Abut- ment and Screw made of Ti6Al4		yes	yes	yes
	Predicate Devices K-Number	K081005	K081005	K081005
9.	Titanium Base	Straumann product catalog page 51. Product-No. 048.505	Product-No. 048.600 (p 55)	Product-No. 048.606
Predicate Device	Diameter	3.5 mm	4.8 mm	6.5 mm
ā.	System	Tissue level NN	Tissue level RN	Tissue level WN
	Manu- facturer	Straumann	Straumann	Straumann
Proposed Device TiBase		SSO 3.5	SSO 4.8	SSO 6.5

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						-Jongs		- 404	
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								tures	
Manu- facturer	System	Diameter	Titanium Base	Predicate Devices					
				K-Number					
			(p 62)				nal		
							Octa-		
							gonal		
	T. C.	3.5 \$ / 4.0	Product-No. 24285	7.081666	Š	3	Inter- nal		same
Astra 1ecn	CsseoSpeed	Smm			3	<u> </u>	Hexa- gonal	ļ	
Astra Tech	OsseoSpeedTM	4.5 / 5.0	Product-No. 24235	K081666	ycs	yes	Inter- nal	yes	same
							Hexa-		

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Screw gco- metry			same	same
Con- nec- tion geo- metry Anti- rota- tional fea- tures			yes	yes
Con- nec- tion geo- metry Type		gonal	Inter- nal Hexa- gonal	Inter- nal Hexa- gonal
Iden- tical con- nec- tion geo- metry to abut- ments			yes	yes
Abutment and Screw made of Ti6Al4	-		yes	yes
	Predicate Devices K-Number		K032158	K032158
9	Titanium Base		Friadent product catalog page 32. Product-No. 46-2132	Product-No. 46-2142
Predicate Device	Diameter		3.4 mm	3.8 mm
<u>G</u>	System		Frialit® / Xive®	Frialit® / Xive®
	Manu- facturer		Friadent	Friadent
Proposed Device TiBase			FX 3.4	FX 3.8

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Proposed		Ā	Predicate Device	93		Abut-	Iden-	Coli	Con	Screw
Device			•			ment	tical	nec-	-sec-	-038
						and	-000	tion	tion	metry
TiBase				-		Screw	nec-	-0ag	-038	
						made	tion	metry	metry	
						of	geo-			
						Ti6Al4	metry			
						^	. 9			_
						,	abut-	Type	Anti-	
									rota-	_
							ments		tional	
									fea-	
									tures	
	Manu-	System	Diameter	Titanium Base	Predicate Devices					
					K-Number					
								Inter-		
								nal		
FX 4.5	Friadent	Frialit® / Xive®	4.5 mm	Product-No. 46-2152	K032158	yes	yes	Heve	yes	same
								IICAG-		
								gonal		
								Inter-		
2 2 4 2	T don't	Eriolis@ / Wive@	5 5 mm	Product-No. 46-2162	K032158	Ves	ves	# T	ves	same
FA 3.3	rnaueni	riidiiw / Aives	111111 C.C	110duct-110; -0-110		3	3	Неха-	}	
								gonal		
BO 3.4	Biomet 3i	Osseotite	3.4 mm	3i Biomet product	K072642	yes	yes	Exter-	yes	same
		(Connec-tion		cataing page 20.						
						-	_	-		

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Manuaria   System   Diameter   Titantum Base   Fredicate   Devices   Fixed   Devices   Fixed   Devices   Fixed   Devices   D		<u> </u>	Predicate Device	ອ		Abut-	Iden-	Con	ĊO CO	Screw
System   Diameter   Titanium Base   Fredicate   Forduct-No.   Forduct-						ment	tical	nec-	nec-	5
System   Diameter   Titanium Base   Fredicate   100   100     System   Diameter   Titanium Base   Fredicate   100   100   100     System   Diameter   Titanium Base   Fredicate   Type   100   100   100   100   100     System   Diameter   Titanium Base   Fredicate   Type   100   100   100   100   100     System   System   System   Titanium Base   Fredicate   Type   100						and	-doo	tion	tion	metry
System   Diameter   Titanium Base   Fredicate   Tipal   metry   Tipal   metry						Screw	nec-	98	960	
Note: Ex. Hex)   System   Diameter   Titanium Base   Predicate   Type   Type   Ex. Hex)   Product-No.   Product-No.   Product-No.   Product-No.   Product-No.   Product-No.   RO72642   Yes   Hexatope: Ex. Hex)   Product-No.   RO72642   Yes   Hexatope: Ex. Hex)   Product-No.   RO72642   Yes   Hexatope: Ex. Hex)   S.0 mm   Product-No.   RO72642   Yes   Yes   Hexatope: Ex. Hex)   Product-No.   Product-No.   RO72642   Yes   Yes   Hexatope: Ex. Hex)   Product-No.   RO72642   Yes   Yes   Hexatope: Ex. Hex)   S.0 mm   Product-No.   RO72642   Yes   Yes   Hexatope: Ex. Hex)   S.0 mm   RO72642   Yes   Yes   Hexatope: Ex. Hex)   S.0 mm   RO72642   Yes   Yes   Hexatope: Ex. Hex)   RO72643   Yes   Yes   Hexatope: Ex						made	tion	metry	metry	
Tibalia   metry   Type   Type: Ex. Hex)   Froduct-No.						ō	-028			
System Dlameter Titanium Base Predicate type: Ex. Hex)  Connec-tion type: Ex. Hex)  Connec-tion type: Ex. Hex)  Connec-tion Connec-tion Connec-tion consecutive Connec-tion co						Ti6Al4	metry			
System         Diameter         Titanium Base         Predicate Devices         R-Number         Predicate Gonne         Predicate Devices         Predicate Device						>	<b>.</b> 0	•		
System   Diameter   Titanium Base   Predicate   Devices   Device							ah int	Type	Anti-	
System         Diameter         Titanium Base         Predicate         Predicate         Predicate         Predicate         Predicate         Predicate         Predicate         Product-No.         MAP32G         K-Number         Hexater           Osseotite         4.1 mm         Product-No.         K072642         yes         yes         Hexater           Osseotite         5.0 mm         Product-No.         K072642         yes         yes         Hexater           Osseotite         5.0 mm         Product-No.         K072642         yes         yes         Hexater           Connection         5.0 mm         WPP552G         K072642         yes         yes         Hexater							-inde		-oto-	
System Diameter Titanium Base Predicate  Devices  K-Number  K-Numb							ments		tional	
System Diameter Titanium Base Predicate  Devices  K-Number  K-Numb		-							T T T	
System Diameter Titanium Base Predicate Devices  K-Number  K-Numbe									rea- tures	
System Diameter Titanium Base Predicate    Name										
type: Ex. Hex)  Osseotite  (Connec-tion type: Ex. Hex)  Osseotite  Osseotite  Osseotite  Osseotite  Osseotite  Osseotite  Osseotite  Connec-tion  \$5.0 \text{ mm}\$  WPP552G  Connec-tion  \$5.0 \text{ mm}\$  WPP552G  WAP32G  K072642  Yes  Yes  Yes  Hexa-gonal  gonal  gonal  Ball  Briter-  Briter-  Briter-  Ball  Briter-   Briter-  Briter-  Briter-  Briter-  Briter-  Briter-  Briter-	mu- urer	System	Diameter	Titanium Base	Predicate Devices					
type: Ex. Hex)  Osseotite  Connec-tion type: Ex. Hex)  Osseotite  Osseotite  Osseotite  Osseotite  Connec-tion type: Ex. Hex)  So man type: Ex. Hex)  Hexa-type: Ex. Hex)  Connec-tion type: Ex. Hex)  Connec-tion type: Ex. Hex)  So man type: Ex. Hexa-type:					K-Number					
Osseotite         4.1 mm         Product-No. (Connec-tion type: Ex. Hex)         K072642         yes         Fxter-nal           Use of the connection type: Ex. Hex)         5.0 mm         Product-No. (K072642         K072642         yes         yes         Exter-nal           Use of the connection type: Ex. Hex)         5.0 mm         WPP552G         K072642         yes         yes         Hexangenal		type: Ex. Hex)		Product-No. MAP32G				Hexa- gonal		
(Connec-tion type: Ex. Hex)         4.1 mm (Connec-tion)         Froduct-No. (R072642)         K072642 (Pes Product-No. (R072642)         Yes Product (Pex Product-No. (R072642)         Hexalization (R072642)		Osseotite		N. S. M. S.				Exter- nal		
Osseotite Connec-tion type: Ex. Hex)  Osseotite  Freduct-No.  WPP552G  WPP552G  Fxter- nal  WPP552G  K072642  yes yes Hexa- gonal	net 3i	(Connec-tion type: Ex. Hex)	4.1 mm	APP452G	K072642	yes	yes	Hexa- gonal	yes	same
(Connec-tion 5.0 mm WPP552G K072642 yes yes Hexatype: Ex. Hex)		Osseotite		Product-No.				Exter- nal		
	net 3i	(Connec-tion type: Ex. Hex)	5.0 mm	WPP552G	K072642	yes	yes	Hexa- gonal	yes	same

Sirona Dental 510(k) Summary

May 06, 2011

geo- metry		same	same	
		es 	Sa	
Con- nec- tion geo- metry Anti- rota- tional fea- tures		yes	yes	
Con- nec- tion geo- metry Type		Inter- nal Hexa- gonal	Inter- nal Hexa- gonal	
Iden- tical con- nec- tion geo- metry to abut- ments	•	yes	yes	
Abut- ment and Screw made of Ti6Al4 V		yes	yes	
	Predicate Devices K-Number	K060880	K060880	
	Titanium Base	Zimmer product catalog page 9. Product-No. ZOA342S	Product-No. ZOA442S	
Predicate Device	Diameter	3.5 mm	4.5 mm	
	System	Tapered Screw- Vent®	Tapered Screw- Vent®	
•	Manu- facturer	Zimmer	Zimmer	į
Proposed Device TiBase		ZTSV 3.5	ZTSV 4.5	

Sirona Dental 510(k) Summary

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					ment	tical	-oeu	nec-	960
			-		and	-doo	tion	tion	metry
			•		Screw	nec-	-0əğ	600	
					made	tion	metry	metry	
					٥	-038			
					Ti6Al4	metry			
					>				
						ohint.	Type	Anti-	
						4041	l 1	-0401	
						ments		Honol	
							•	fea-	
								tures	
Manu- facturer	System	Diameter	Titanium Base	Predicate Devices					
		·		K-Number					
	Tapered Screw-		Product-No. ZOA562S	000000			Inter- nal		
Zimmer	Vent®	5.7 mm		K060880	yes	yes	:	yes	same
							Hexa- gonal		
	•		Nobel Biocare product				Inter- nal		
			15				Цохо		
Nobel Biocare	Nobel Active NP	3,5mm	Catalog page /1.	K102436	yes	yes	nexa-	yes	same
			Product-No.				j 0		
			34194						

nary

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		Predicate Device	ce		Abut-	Iden-	Cop	Con-	Screw
	,				ment	tical	nec-	nec-	900
				٠,	pue	-000	tion	tion	metry
					Screw	nec-	-beg	geo-	
					made		metry	metry	
					ě				
					Ti6Al4	_			
					>			•	
						•	Type	Anti-	
								rota-	
						SINCE		-1000	
								rea-	
								tures	
			,	:					
Manu- facturer	System	Diameter	litanium Base	Predicate Devices			•		
				K-Number			•		
							Inter-		
		4,3/	Product-No.	7.1007436	3971	36%	nal	Sev	dues
Nobel Biocare	Nobel Active K.F.	5,0mm	34198	0C+701V	£	Š	Hexa-	S	
							gonal		
			Straumann product				Inter-	:	
			Catalog				slots		
Straumann	Bone Level NC	3,3mm		K062129	yes	yes		yes	same
			Product-No.						
			022.2102						

Sirona Dental 510(k) Summary

Pronoced			Predicate Device	95		Abut-	Iden-	Con-	Con-	Screw
Device						ment	tical	nec-	nec-	960
,						and	-000	tion	tion	metry
TiBase						Screw	Dec-	-036	-bag	
						made	tion	metry	metry	
						of	geo-			
	•					Ti6Al4	metry			
						>	Ş			
							abut-	Type	Anti-	
						-			rota-	
							ments		tional	
									fea-	
									tures	
	Manu-	System	Diameter	Titanium Base	Predicate					
	facturer				Devices					
					K-Number					
			4,1/	Product-No.	0010707		90/1	Inter-	90,1	omes
S BL 4.1	Straumann	Bone Level RC	4,8mm	022.4102	671700	3	2	slots	<u> </u>	,
				Biomet product				Inter-		
				,				nal		,
B C 3.4	Diamet 3:	Certain	3 4mm	Catalog page 5	K073345	ves.	ves ves	Hexa-	s Ace	same
	ic milora		,	Product-No.		•	•	gonal	•	
				IMAP32G						
								10,5		
B C 4.1	Biomet 3i	Certain®	4,1mm	Biomet product	K073345	yes	yes	nal	yes	same

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Sirona Dental 510(k) Summary

Proposed		4	Predicate Device	ec.		Abut-	Iden-	Con-	Con-	Screw
Device						ment	tical	nec-	nec-	-oəg
•						pue	-000	tion	tion	metry
TiBase						Screw	nec-	986	-626	
						made	tion	metry	metry	
						Jo	-03g			
						Ti6Al4	metry			
						>	9			
							abut-	Type	Anti-	
							ments		rota-	
									tional	
									fea-	
									tures	
	Manu-	System	Diameter	Titanium Base	Predicate					
	facturer				Devices					
					K-Number					
				Catalog page 5				Неха-		
	•			Product-No.				gonal		
				IAPP452G						
				Biomet product				Inter-		
-				,	-			nal		
0 0 0	Biómet 3:	erieine)	\$ 0mm	Catalog page 5	K073345	89	Ves	Неха-	8	same
2				Product-No.		•		gonal		
				IWPP562G						

Sirona Dental 510(k) Summary

Table 6: Comparison of InCoris ZI meso to Predicate Device

Intended use	inCoris Zlimeso inCoris Zl meso blocks are used in manufacturing individually designed mesostructures, which are glued to a fitting titanium base after milling and sintering.	inCorfs ZI meso (IXIODIS2)  inCoris ZI meso blocks are used in manufacturing individually designed mesostructures, which are glued to a fitting titanium base after milling and sintering.
Application .	inCoris ZI mesostructures can only be used for the intended titanium bases or implants.  Allocation of the connection size to the respective titanium base can be determined by the scanbody set of the respective implant system.	inCoris ZI mesostructures can only be used for the intended titanium bases or implants. Allocation of the connection size to the respective titanium base can be determined by the scanbody set of the respective implant system.  Please observe the indications
	and contraindications of the implant.	and contraindications of the implant.
Contra-Indications	<ul> <li>Insufficient oral hygiene</li> <li>Insufficient space available</li> <li>Bruxism</li> <li>For mesostructure-geometry with angulation correction greater than 20° to the implant axis</li> <li>For mesostructure-geometry with angulation correction to the implant axis for Camlog only</li> <li>For individual tooth restorations with free end saddle</li> <li>For restorations with a length to implant length ratio of more than 1:1.25</li> </ul>	<ul> <li>Insufficient oral hygiene</li> <li>Insufficient space available</li> <li>Bruxism</li> <li>For restorations with angulation correction to the implant axis</li> <li>For individual tooth restorations with free end saddle</li> <li>For restorations with a length to implant length ratio of more than 1:1.25</li> </ul>
Technical Data		
Block-Material Composition	<ul> <li>ZrO2+HfO2+Y2O3:</li> <li>&gt;99.0%</li> <li>Y2O3: 5.2%</li> <li>HfO2: 2%</li> </ul>	<ul> <li>ZrO2+HfO2+Y2O3:</li> <li>&gt;99.0%</li> <li>Y2O3: 5.2%</li> <li>HfO2: 2%</li> </ul>

	inCoris ZIImeso	inCorts A' meso (13000152)
	• Al2O3: ≤ 0.05%	• Al2O3: ≤ 0.05%
	• Fe2O3: 0.3%	• Fe2O3: 0.3%
Density (sintered)	6.06 g/cm <sup>3</sup>	6.06 g/cm <sup>3</sup>
Coefficient of thermal	11.0*10 <sup>-6</sup> K <sup>-1</sup>	11.0*10 <sup>-6</sup> K <sup>-1</sup>
expansion (CTE)	(20 °C - 500 °C)	(20 °C - 500 °C)
Flexural strength	> 900MPa	> 900MPa
Fracture toughness (K <sub>IC</sub> )	5.8 MPa·m <sup>1/2</sup>	5.8 MPa·m <sup>1/2</sup>
Grain Size	about 0.5 μm	about 0.5 μm
Bonding Material	Panavia F 2.0	Panavia F 2.0
	(www.kuraray-dental.de)	(www.kuraray-dental.de)

Table 7: Comparison of Sirona Dental CAD/CAM Design and fabricating Devices to Predicate Devices

	Shoun	Store
	Dental CADACAM Designed	Denei CADICAN Deseponi
	(abitetineDates)	* Christing Davies
		(LICUSE)
Used for	The Sirona Dental CAD/CAM-	The Sirona Dental CAD/CAM-
Osed for	System is indicated for taking	System is indicated for taking
	optical impressions to record the	optical impressions to record the
	topographical characteristics of	topographical characteristics of
,	teeth, dental impressions, or stone	teeth, dental impressions, or stone
	models by computer aided design	models by computer aided design
ł	and fabrication in patients that	and fabrication in patients that
	require dental restorative	require dental restorative
·	prosthetic devices. The system	prosthetic devices. The system
	also features the processing of	also features the processing of
	mesostructures, a dental	mesostructures, a dental
	restorative prosthetic device used	restorative prosthetic device used
	in conjunction with endosseous	in conjunction with endosseous
	dental implant abutments.	dental implant abutments.
	Sirona Dental CAD/CAM Design	Sirona Dental CAD/CAM Design
	and fabricating devices feature the	and fabricating devices feature the
	processing of mesostructures, a	processing of mesostructures, a
	dental restorative prosthetic	dental restorative prosthetic
	device used in conjunction with endosseous dental implant	device used in conjunction with endosseous dental implant
	abutments, i.e. it is an accessory	abutments, i.e. it is an accessory
	to it. Devices which feature the	to it. Devices which feature the
	processing of mesostructures	processing of mesostructures
	comprises CEREC3, CEREC AC,	comprises CEREC3, CEREC AC,
	inEos, inEos Blue, CEREC MCXL and inLab MCXL	inEos, inEos Blue, CEREC MCXL and inLab MCXL
	MCAL and IIILab MCAL	WICAL and mean MCAL
Used with	Sirona Dental CAI/CAM	Sirona Dental CAI/CAM
	Hardware	Hardware
		· .
Controlling of recording process (CAI)	Yes	Yes
(optical impression)		
Processing the recorded	Yes	Yes

data (data of optical impression) (CAD)	Shòid Danil (CADICANI Delgaèni) Àbhanng Divissi	(ENOUS) (CANOSAMIDATES (Instruction Davies)
Export of milling data to milling machine	Yes	Yes
Administration of patient data	Yes	Yes
Further functions	Calibration of CAI/CAM hardware	Calibration of CAI/CAM hardware
Online capability	Option to upload/download the data from a web portal (Cerec Connect), to have CAI and CAM operating on two different locations connected via Internet	Option to upload/download the data from a web portal (Cerec Connect), to have CAI and CAM operating on two different locations connected via Internet
Scan Implant Interface/surface	Yes (or with mounted scanbody)	Yes (or with mounted scanbody)
Scan custom wax-up	Yes	Yes
Preparation of individual restoration ("meso-structure") to be mounted on the abutment	Yes	Yes
Bond of milled ziconia/ceramic individual meso-structure to metal abutment	Yes	Yes
Create of fitting crown to be mounted on top of meso-structure	Yes	Yes
Used with	Sirona Dental CAI/CAM Hardware	Sirona Dental CAI/CAM Hardware

	Shon Daned CADACANAD signend Rucksing Devices	Shone Danni CAD/CAD/Disignani febric (Divisi) (CIOISI)
Used for	CAD creation of dental restorations including inlays, onlay, venners, crowns, bridges and meso-structure to be mounted on top of abutments	CAD creation of dental restorations including inlays, onlay, venners, crowns, bridges and meso-structure to be mounted on top of abutments
Controlling of measurement process (CAI)	Yes	Yes
Processing the measurement data (CAD)	Yes	Yes
Export to milling machine	Yes	Yes
Administration of patient data	Yes	Yes
Further functions	Calibration of CAI/CAM hardware	Calibration of CAI/CAM hardware

## 7 Nonclinical Testing

According to FDA Guidance "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments", May 12, 2004, fatigue testing has been performed for angled abutments. A reverse-engineering analysis has demonstrated that the devices are identical with their predicates and compatible with their mating implants.

Software validation testing has been performed according to IEC 62304:2006. A warning has been added warning the user that abutments with an angle of greater than 20° are out of specification.

## 8 Clinical Testing

Clinical testing is not required and has not been performed.

# 9 Conclusion

Based on a comparison of intended use, indications, construction materials, principal of operations, features and technical data, the Sirona Dental CAD/CAM System which comprises of titanium bases TiBase, inCoris ZI meso blocks and Sirona Dental CAD/CAM Design and fabricating devices are safe and effective their intended use and perform as well as and are substantially equivalent to their Predicate Devices.





Food and Drug Administration 10903 New Hampshire Avenue Document Control Room –WO66-G609 Silver Spring, MD 20993-0002

Mr. Fritz Kolle Sirona Dental Systems GmbH Fabrikstrasse 31 Bensheim Germany D-64625

FEB 1 7 2012

Re: K111421

Trade/Device Name: Sirona Dental CAD/CAM System

Regulation Number: 21 CFR 872.3630

Regulation Name: Endosseous Dental Implant Abutment

Regulatory Class: II Product Code: NHA Dated: February 14, 2012 Received: February 16, 2012

#### Dear Mr. Kolle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <a href="http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ducm115809.htm">http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ducm115809.htm</a> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <a href="http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm">http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm</a> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <a href="http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm">http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm</a>.

Sincerely yours,

Anthony D. Watson, BS, MS, MBA

Director

Division of Anesthesiology, General Hospital, Infection Control and Dental Devices Office of Device Evaluation Center for Devices and Radiological Health

510(k) Number (i	f known):	
Device Name:	Sirona Dental CAD/CAM Sys	eem
Indications for Us	se:	·
system consists Specifically, to which is used aesthetics in th Camlog Titan System. The C	I maxillae in support of single or multiputs of three major parts: TiBase, InCoris the InCoris mesostructure and TiBase contains a conjunction with endosseous denote oral cavity. The InCoris mesostructure itum base CAD/CAM (types K2244.x. CAD/CAM software is intended to designesostructure and TiBase two-piece above.)	for use in partially or fully edentulous de-unit cement retained restorations. The mesostructure, and CAD/CAM software. Imponents make up a two-piece abutment tal implants to restore the function and the may also be used in conjunction with the exxx) (K083496) in the Camlog Implant and fabricate the InCoris mesostructure.
<ul> <li>No</li> <li>Fr</li> <li>Bi</li> <li>As</li> <li>Zi</li> <li>St</li> <li>St</li> <li>Bi</li> </ul>	obel Biocare Replace (K020646) obel Biocare Branemark (K022562) iadent Xive (K013867) iomet 3i Osseotite (K980549) stra Tech Osseospeed (K091239) mmer Tapered Screw-Vent (K061410) raumann SynOcta (K061176) raumann Bone Level (K053088) iomet 3i Certain (K014235) obel Biocare Active (K071370)	(Division Sign-Off)  Division of Anesthesiology, General Hospita Infection Control, Dental Devices  510(k) Number: K111421
Sirona Dental Sy Sirona Dental Ca	vstems 510(k) May 0 AD/CAM System	5, 2011 Page x